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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,482	03/18/2004	Brett P. Monia	BIOL0003US.P1	6288
71476	7590	10/18/2007		
McDermott Will & Emery 4370 La Jolla Village Drive Suite 700 San Diego, CA 92122			EXAMINER MCGARRY, SEAN	
			ART UNIT	PAPER NUMBER
			1635	
			MAIL DATE	DELIVERY MODE
			10/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/803,482

Applicant(s)

MONIA ET AL.

Examiner

/Sean R. McGarry/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 02 April 2007 and 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 24-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 23, 64 and 66 is/are rejected.
- 7) ☒ Claim(s) 65 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/15/07, 7/09/07</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Applicant's election with traverse of SEQ ID NO:33 in the reply filed on 7/09/07 is acknowledged. The traversal is on the ground(s) that a search of claim 1 requires a search of the oligonucleotides of claim 6. Due to the complex nature of Sequence searching and due to the multiple SEQ IDs recited in the claim, several different searches and separate considerations of those searches would be required to examine the claims appropriately. Applicant is directed to the below rejections as an indication of the burden of searching and examining each of the recited sequences. It is noted that both the broad claim and claims based on the elected sequence are rejected under art. A different search and consideration is required for each claimed SEQ ID. The search of sequences is complex and becomes a burden in the examination process. It is noted that the search includes a search for oligonucleotides that have an 8-nucleobase portion of the recited SEQ ID. However, SEQ ID NO: 32 will be examined in this Official Action with SEQ ID NO: 33.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-22 and 24-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/08/06.

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SEQ IDs other than SEQ ID NO: 33 and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/09/07.

Applicant arguments filed 4/02/07 have been considered but are moot in view of the amendments made to the claims and the new grounds of rejection set forth below.

Claim 65 is objected to as being dependent upon a rejected base claim and reciting non-elected subject matter, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and deleting the non-elected subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18, 23, 64, and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has added the limitation "400-511 of SEQ ID NO: 4". Applicant has pointed to page 20 and to Table 1 for support for this range. Table 1 does not provide bases for the point "400" in the range and page 20 provides support for ranges "351-400", "401-450", "451-500", and "501-550". The specification and claims as originally filed fail to provide apparent support for the recited range of "400-501". If applicant believes that support for this range exists applicant should point to such support with particularity.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-14, 23, 64, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Goh et al [US 5,708,160].

Goh et al disclose SEQ ID NOS 25 and 75. SEQ ID NO: 75 comprises at least 8 nucleotides targeted [antisense to] to nucleotides 400-511 of SEQ ID NO:4 [of the instant invention], SEQ ID NO: 75 is an oligonucleotide that is DNA. SEQ ID NO: 75 has

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a region that is at least 89.5% similar to the region targeted where at least an 8-nucleobase portion is 100% identical. SEQ ID NO: 25 comprises at least 8 nucleotides targeted [antisense to] to SEQ ID NO:4 [of the instant invention], SEQ ID NO: 25 is an oligonucleotide that is DNA. SEQ ID NO: 25 has a region that is at least 93.8% similar to the region targeted where at least an 8-nucleobase portion is 100% identical. Kits are disclosed for the storage and use of the oligonucleotides of their invention [see claim 9, for example]. Both SEQ ID NO: 25 and 75 have at least an eight-nucleobase portion of SEQ ID NO: 33.

The compounds of the prior art meet all of the structural limitations set forth in the claims. The activity required by the claims can not be determined by the examiner and the burden is shifted to applicant to show that the compounds of the prior art do not poses the required function of the claimed invention (see below).

Claims 1-18, 23, 64 and 65 rejected under 35 U.S.C. 102(e) as being anticipate by Monia et al [US 6,867,039].

Monia discloses SEQ ID NO:22 which is 100% complimentary to residues 2-20 of SEQ ID NO: 32 of the instant invention and therefore is targeted to at least and 8 nucleotide portion of nucleotides 400-511 of SEQ ID NO: 4. The compounds of Monia are disclosed to be antisense oligonucleotides that target mRNA, for example. The oligonucleotides described by Monia posses all the limitations set forth in the claims, including the specified modification. See column 6 where "RNA" and "DNA" is disclosed.

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At columns 7-12 all of the modifications recited in the claims are disclosed. "Kits" are disclosed at column 5.

The compounds of the prior art meet all of the structural limitations set forth in the claims. The activity required by the claims can not be determined by the examiner and the burden is shifted to applicant to show that the compounds of the prior art do not poses the required function of the claimed invention (see below).

**A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Sean R. McGarry/ whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean R McGarry/  
Primary Examiner  
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